

NOV 22 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Submitter:

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Date Prepared: 3/28/2011

Device Name: AnyRidge Internal Implant System

Device Information:

Device Name: AnyRidge Internal Implant System
Classification Name: Implant, Endosseous, Root-Form
Common Name: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Subsequent Product Code: NHA
Regulation number: 21 CFR 872.3640

Device Description

The AnyRidge Internal Implant System is especially designed for use in dental implant surgery. It consists of machined titanium, screw-form, rootform endosseous dental implant. The AnyRidge Internal Implant System contains two types of fixtures, Normal ridge type and low ridge type, various abutments and instruments. This system is made from pure titanium and the surface treatment is done with R.B.M. The implants are used to replace missing teeth in various situations ranging from a single missing tooth to the completely edentulous individual. The wide ranges of size are provided to be in conformance with each patient, or to cover up in case of due to deficiency in implant operation. The system is used as two stage, root-form dental implants, associated with abutment systems, which provide the clinician with the screw (for UCLA abutments) and cement (for solid abutments) retained restoration for multi-mount options. This system has 4.0, 4.4, 4.9, 5.4, 5.9mm diameters for normal ridge and 6.4, 6.9, 7.4, 7.9, 8.4mm diameters for low ridge fixtures. In addition, this system has 7.7, 9.2, 10.7, 12.2, 14.20, 17.20mm lengths for normal ridge and 7.9, 9.4, 10.9, 12.4, 14.4mm lengths for low ridge fixtures.

Fixtures, the prosthetics, and the surgical instruments are produced and packaged separately. All included devices in the system are covered by this submission.

Indication for use

The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than $\phi 6.0$ mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

Non-Clinical Test Data

Fatigue testing is performed successfully in accordance with ISO 14801 standard.

Predicate devices

- EZ Plus Implant system (K070562)
- Rescue Internal Implant system (K073058)

The AnyRidge Internal Implant System has a substantially equivalent intended use as the identified predicates. All Implant System are used for mandible and maxilla endosseous dental implant and accessories. The AnyRidge Internal Implant System is similar in fundamental scientific technology to the predicate devices in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium. The subject and predicate devices are similar in size, surface treatment and materials. When compared with predicate devices, no new questions of safety or effectiveness have been raised for the AnyRidge Internal Implant System.

Substantial Equivalence Comparison

		Subject Device	Predicate Device	
510(k) Number		Not available yet	K070562	K073058
Device Name		AnyRidge Internal Implant System	EZ Plus Implant System	Rescue Internal Implant System
Manufacturer		MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd	MegaGen Implant Co., Ltd
Indications for Use		Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design		AnyRidge Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex	EZ Plus Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal and External Hex	Rescue Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Tri-lobe type indexing feature Anti-rotational type
Material		CP4 Titanium and its alloy	Commercial pure titanium	CP4 Titanium and its alloy
Sterilization		Gamma sterilization	Gamma sterilization	Gamma sterilization
Fixture Diameter		Internal type 4.0, 4.4, 4.9, 5.4, 5.9mm (For normal ridge) 6.4, 6.9, 7.4, 7.9, 8.4mm (For low ridge)	Internal type: 3.3, 4.0, 5.0mm External type: 3.3, 4.0, 5.0mm	Internal Type 6.0, 6.5, 7.0, 7.5, 8.0mm
Fixture Height		Internal type 7.7, 9.2, 10.7, 12.2, 14.20, 17.20mm (For normal ridge) 7.9, 9.4, 10.9, 12.4, 14.4mm (For low ridge)	Internal type: 8.0, 10.0, 11.0, 13.0, 15.0, 18.0mm External type: 8.0, 10.0, 11.0, 13.0, 15.0, 18.0mm	Internal type 5.0, 6.0, 7.0mm
Abutment	Diameters	Ø4.0-10.0mm	Ø4.0-6.0mm	Ø6.0-10.0mm
	Lengths	8.4-16.4mm	9.0-17.2mm	8.3-14.65mm

Product Code	DZE, NHA	DZE, NHA	DZE
Surface treatment	RBM	RBM	RBM
Angulations of Angled abutments	15, 25°	15, 25°	N/A

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification EZ Plus Implant system (K0705625) and Rescue Internal Implant system (K073058) concludes that the new device, Anyridge Internal Implant System performs well or better than predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Megagen Company, Limited
C/O Ms. April Lee
Consultant / US Agent
KoDent, Incorporated
325 North Puente Street, Unit B
Brea, California 92821

NOV 22 2011

Re: K110955
Trade/Device Name: AnyRidge Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 19, 2011
Received: October 24, 2011

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony D. Watson'.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K110955

Device Name: AnyRidge Internal Implant System

Indication for use :

The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than $\phi 6.0$ mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

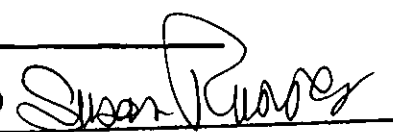
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

OverThe-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)Division of Anesthesiology, General Hospital
Infection Control, Dental Devices510(k) Number: K110955